FB 19 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

pplication of: Dixit, et. al. Docket No.: PF335D2

Serial No.: 09/961,201 Art Unit: 1644

Filed: September 24, 2001 Examiner: P.N. Huynh

Title: Interleukin-1 Beta Converting

Enzyme Like Apoptosis Protease 6

Statement Concerning the Deposited cDNA Clone

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Date: 19 February 2004

Sir:

The undersigned attorney of record hereby states:

- 1. A plasmid containing human cDNA encoding human Interleukin-1 Beta Converting Enzyme Like Apoptosis Protease 6 polypeptide was deposited under the terms of the Budapest Treaty on May 30, 1996 at the American Type Culture Collection (ATCC), Patent Depository, 10801 University Boulevard, Manassas, Virginia 20110-2209 (current address), and given accession number 97590.
- 2. Assurance is hereby given that: (1) the deposit was made under terms of the Budapest Treaty; (2) except for the limitations allowed by 37 C.F.R. § 1.808(b), all restrictions on the availability to the public of the deposit will be irrevocably removed upon the granting of a patent from the captioned application; (3) the deposit has been made under conditions such that access to the material will be available during the pendency of the captioned patent application to one determined by the Commissioner; and (4) the deposit will be maintained with the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposit, and in any case, for a period of at least thirty years after the date of deposit or for the enforceable life of the patent, whichever period is longer.

Respectfully submitted

Lin J. Hymel (Reg. No.45,414)

Attorney for Applicants

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 908-768 ATCCROVE • FAX: 301-816-4366

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

RECEIVED

JUN 1 1 1995

HGS PATENT DEPT.

To: (Name and Address of Depositor or Attorney)

Human Genome Sciences, Inc. Attn: Robert H. Benson, Ph.D., J.D. 9410 Key West Avenue Rockville, MD 20850

Deposited on Behalf of: Human Genome Sciences, Inc.

Identification Reference by Depositor:

ATCC Designation

DNA plasmid 1290857 PF343 5 B DNA plasmid 1095150 PF34 7.5B

97589 97590 ¹

The deposits were accompanied by: __ a scientific description _a proposed taxonomic description indicated above.

The deposits were received May 30, 1996 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested June 6, 1996. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Barbara M. Hailey, Administrator, Patent Depository

Date: June 6, 1996



American Type Culture Collection

12301 Parklawn Drive, Rockville, MD 20852 USA, Telephone (301) 231-5520 Fax (301) 816-4366

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

	Plasmid
Strain	designation (i.e., number, symbols, etc). 1095150
Is this	an original deposit under the Budapest Treaty? Yes
Is this	a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Trea- please indicate ATCC designation. <u>NO</u>
_	No No
Provide	details necessary to cultivate, test for viability and store deposit. It mixture, provide tests and a method to check presence.
	ee instructions attached as Appendix A
	e an indication of the properties of the strain which are or may be dangerous to health or the environment. aware of any such properties
Provid	descrit properties (e.g., Gram negative rod).
<u>n/a</u>	is it being cultured in the presence of antibiotics? If so, please list
	a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list antibiotics.
	a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list antibiotics.
	a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list antibiotics. b. If deposit is hybridoma, what is the isotype of antibody produced? phytopathogenic? n/a
Is thi	a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list antibiotics. b. If deposit is hybridoma, what is the isotype of antibody produced? strain zoopathogenic? n/a phytopathogenic? n/a E COMPLETED) Packaging Class I, II, III, IV [In accordance with U.S. Public Health Services Regulation 42 C.F.
Is thi (MUST § 72.3	a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list antibiotics. b. If deposit is hybridoma, what is the isotype of antibody produced? strain zoopathogenic? n/a phytopathogenic? n/a ECOMPLETED) Packaging Class I, II, III, IV [In accordance with U.S. Public Health Services Regulation 42 C.F. (a)-(f)17
Is this (MUST) § 72.3	a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list antibiotics. b. If deposit is hybridoma, what is the isotype of antibody produced? strain zoopathogenic? n/a phytopathogenic? n/a ECOMPLETED) Packaging Class I, II, III, IV (In accordance with U.S. Public Health Services Regulation 42 C.F. (a)-(f)17
Is this (MUST) § 72.3 Does to If so, Molecu Isolate	a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list antibiotics. b. If deposit is hybridoma, what is the isotype of antibody produced? strain zoopathogenic? n/a phytopathogenic? n/a ECOMPLETED) Packaging Class I, II, III, IV [In accordance with U.S. Public Health Services Regulation 42 C.F (a)-(f)1? This strain contain plasmids relevant to the patent process? Yes what physical containment level is required (National Institutes of Health Guidelines Involving Recombinant less, i.e., P1, P2, P3 or P4 facility)? P1
Is this (MUST) § 72.3 Does to If so, Molecu Isolate	a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list antibiotics. b. If deposit is hybridoma, what is the isotype of antibody produced? strain zoopathogenic? n/a phytopathogenic? n/a DE COMPLETED) Packaging Class I, II, III, IV [In accordance with U.S. Public Health Services Regulation 42 C.F. (a)-(f)1? This strain contain plasmids relevant to the patent process? Yes What physical containment level is required (National Institutes of Health Guidelines Involving Recombinant less, i.e., P1, P2, P3 or P4 facility)? P1
Is this (MUST) § 72.3 Does to If so, Molecu Isolati	a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list antibiotics. b. If deposit is hybridoma, what is the isotype of antibody produced? strain zoopathogenic? n/a phytopathogenic? n/a ECOMPLETED) Packaging Class I, II, III, IV [In accordance with U.S. Public Health Services Regulation 42 C.F (a)-(f)1? This strain contain plasmids relevant to the patent process? Yes what physical containment level is required (National Institutes of Health Guidelines Involving Recombinant less, i.e., P1, P2, P3 or P4 facility)? P1

FEES: 30 years' storage \$600. 30 years' notification \$360. Viability testing \$100 to \$400 or quoted price, dependent upon necessary material and/or equipment. Expedite ATCC number \$10. Return sample for approval (if not submitted frozen or freezerecessary material analog equipment. Expedite Arec remove allo Return sample for approval (IT INC Supples outside U.S.A.

Prior t	U.S. Patent issues, ATCC makes the culture available to anyone who requests it, as allowed under U.S. la o issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or releg office. In addition to those entitled to a sample under the Budapest Treaty and the European Patent Convention wish the strain made available:
a.	As of the date of deposit to anyone who requests a culture? (If "yes", there are no restrictions distribution from date of deposit or conversion to 8udapest). NO
ь.	To requestors which satisfy Patent Offices in countries not signatory to the Budapest Treaty? If "yes", ple state which countries.
	Yes, Canada, South Africa, Israel, Mexico
Do you	wish ATCC to inform you of all requests for this strain? (\$360 fee for 30-year informing). Yes
Would y	ou like expedited notification of your ATCC number? (\$10 fee). ATCC must observe viability first.
Name of	Individual. Robert H. Benson, Ph.D., J.D.
Fax No.	(301) 309-8512 Telephone No. (301) 251-6015
have bee	by check, or credit card (MasterCard or VISA), must accompany the deposit unless prior arrangements for bill in made and approved. If arrangements have been made to bill you for services, please indicate person who sho invoice. Also, please include 9.0. number.
<u>Tina</u> 9410	Powers c/o Human Genome Sciences, Inc. Kev West Avenue
Rock	ville, Maryland 20850
	print the name shown on credit card Signature
Veme and	address of your attorney of record. Robert H. Benson, Ph.D., J.D.
Human	Genome Sciences, Inc., 9410 Key West Avenue, Rockville, Maryland 20850
PUST BE	COMPLETED. Owner of deposit. (Verify with your management who owns the deposit. The owner is usually a compature, and normally is not an individual.) HUMAN GENOME SCIENCES. INC.
9410	Key West Avenue, Rockville, MD 20850
Addition	at comments. PF304.SB
	tand and agree that the deposit may not be withdrawn by me for a period specified in Rule 9.1 of the Budgo at least 30 years after the date of deposit and 5 years after the date of the most recent request for
deposit)	and that if a culture should die or be destroyed during the life of the patent, or the period of the
vinses.	cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity to for the period of time specified above.
Typed Nan	Robert H. Benson Signature Robert Reusen Date MAY 30, 1996
Address.	9410 Key West Avenue
	Rockville, MD 20850

THIS FORM MUST BE COMPLETED IN ENGLISH

ODRESS SHIPMENTS AND FORM TO THE ATTENTION OF:

Ms. Annette L. Bade, Esq. American Type Culture Collection 12301 Parkiaum Drive Rockville, MD 20852 U.S.A. poder the Paperwork Reduction Act of 1995, no persons are required to re

PTO/SB/17 (10-03)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003, Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

OTAL AMOUNT OF PAYMENT

espond to a collection of informat	tion unless it displays a valid OMB control number.
Con	nplete if Known
Application Number	09/961,201
Filing Date	September 24, 2001
First Named Inventor	Vishva M. Dixit
Examiner Name	P. N. Huynh
Art Unit	1644
Attorney Docket No.	PF335D2

TOTAL AMOUNT OF PATIMENT (\$) 540,00 AMOUNT DOCKSTNO. 11 555D2					
METHOD OF PAYMENT (check all that apply)			FEE	CALCULATION (continued)	
Check Credit Money Order Other None	3. ADDIT	TIONAL	FEES		
χ Deposit Account:					
Deposit 00 0405	Large Entit		I Entity	<u>-</u>	
Account Number 08-3425	Fee Fee Code (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
Deposit Account Human Genome Sciences, Inc.	1051 130	2051	65	Surcharge - late filing fee or oath	
Name The Director is authorized to: (check all that apply)	1052 50	2052	25	Surcharge – late provisional filing fed sheet.	e or cover
X Charge fee(s) indicated below X Credit any overpayments	1053 130	1053	130	Non-English specification	
X Charge any additional fee(s) or any underpayment of fee(s)	1812 2,520	0 1812	2,520	For filing a request for ex parte reexami	ination
Charge fee(s) indicated below, except for the filing fee	1804 920	1804	920*	Requesting publication of SIR prior t Examiner action	to
to the above-identified deposit account.	1805 1,840	1805	1,840*	Requesting publication of SIR after Examiner action	
FEE CALCULATION	1251 110	2251	55	Extension for reply within first month	,
1. BASIC FILING FEE	1252 420	2252	210	Extension for reply within second mo	onth
Large Entity Small Entity	1253 950	2253	475	Extension for reply within third monti	h ·
Fee Fee Fee Fee Fee Pee Pee Paid Code (\$) Code (\$)	1254 1,480	2254	740	Extension for reply within fourth mon	nth
1001 770 2001 385 Utility filing fee	1255 2,010	2255	1,005	Extension for reply within fifth month	,
1002 340 2002 170 Design filing fee	1401 330	2401	165	Notice of Appeal	
1003 530 2003 265 Plant filing fee	1402 330	2402	165	Filing a brief in support of an appeal	-
1004 770 2004 385 Reissue filing fee	1403 290	2403	145	Request for oral hearing	
1005 160 2005 80 Provisional filing fee	1451 1,510	1451	1,510	Petition to institute a public use proc	eeding
SUBTOTAL (1) (\$) 0.00	1452 110	2452	55	Petition to revive - unavoidable	
30B101AL(1) (4) 0.00	1453 1,330	2453	665	Petition to revive - unintentional	
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	1501 1,330	2501	665	Utility issue fee (or reissue)	
Extra Fee from Claims below Fee Paid	1502 480	2502	240	Design issue fee	
Total Claims 63 -43** = 20 x 18.00 = 360.00	1503 640	2503	320	Plant issue fee	
Independent 8 -8** = x = 0.00	1460 130	1460	130	Petitions to the Commissioner	
Claims 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	1807 50	1807	50	Processing fee under 37 CFR 1.17(c	۱)
Large Entity Small Entity	1806 180	1806	180	Submission of Information Disclosure	e Stmt 180.00
Fee Fee Fee Code (\$) Fee Description	8021 40	8021	40	Recording each patent assignment property (times number of properties	
1202 18 2202 9 Claims in excess of 20	1809 770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	· ——
1201 86 2201 43 Independent claims in excess of 3	1810 770	2810	385	For each additional invention to be	
1203 290 2203 145 Multiple dependent claim, if not paid 1204 86 2204 43 ** Reissue independent claims				examined (37CFR 1.129(b))	
1204 86 2204 43 ** Reissue independent claims over original patent	1801 770		385	Request for Continued Examination	(RCE)
1205 18 2205 9 ** Reissue claims in excess of 20	1802 900	1802	900	Request for expedited examination of a design application	Į l
and over original patent	Other fee (sp	ecify)			
SUBTOTAL (2) (\$) 360.00	*Reduced by	/ Basic Fi	ling Fee	Paid SUBTOTAL (3)	\$) 180.00
**or number previously paid, if greater, For Reissues, see above	L				

SUBMITTED BY				(Complete	(if applicable))
Name (Print/Type) Li	n J. Hymel	Registration No. (Attorney/Agent)	45,414	Telephone	(301) 251-6015
Signature	Li 1. Agmi	ℓ		Date	February 19, 2004

